

Department of State Health Services
Council Agenda Memo for State Health Services Council
May 21-22, 2014

Agenda Item Title: Amendments to rules concerning the reporting of preventable adverse events

Agenda Number: 4.c

Recommended Council Action:

☐ For Discussion Only

☒ For Discussion and Action by the Council

Background:

The Emerging and Acute Infectious Disease Branch is responsible for implementing the proposed amended rules. The Branch is located within the Infectious Disease Control Unit, Infectious Disease Prevention Section in the Disease Control and Prevention Services Division. The Branch manages infectious disease surveillance activities for approximately 50 reportable conditions and assists local and regional health departments in disease control and prevention activities.

Health and Safety Code, Chapter 98, requires DSHS to establish a reporting system for health care-associated infections (HAIs) and preventable adverse events (PAEs), and requires the reporting system to collect data through a secure, electronic interface. 25 TAC Chapter 200 specifies the reporting requirements for the HAI/PAE program. The program within the Branch implements and manages HAI/PAE reporting by general hospitals and ambulatory surgical centers.

Summary:

The purpose of the amendments is to comply with Health and Safety Code, Chapter 98 that requires health care facilities to report certain PAEs to DSHS. The statute requires DSHS to make available to the public a report that includes types of PAEs by facility, including the number of deaths or severe harm that resulted from receiving medical care in that facility.

The amendments will require the facility to report PAEs to DSHS indicating whether the event resulted in or was associated with the death of the patient while being cared for in a health care facility. The reporting period for certain PAEs as described in Section 200.7 is scheduled to begin on January 1, 2015.

The rule changes will allow the public to have open knowledge of the number of deaths and severe harm events as a result of PAEs. This knowledge will allow the public to be more informed and make better decisions about choosing a facility. It is expected that facilities will improve their patient safety processes in order to decrease their PAEs, thereby reducing the chance of death or severe harm.

Key Health Measures:

Data will be monitored on a quarterly basis and it will be determined if health care facilities are reporting the data. The data will be recorded by the facility through the current Texas Health Care-Safety Network (TxHSN) system within DSHS. The current baseline for Texas facilities is unknown. After the rule changes take effect, DSHS will be able to determine the average, minimum, and maximum number of deaths or severe harm resulting in or associated with specified PAEs on an annual basis in health care facilities.

Summary of Input from Stakeholder Groups:

The Infectious Disease Control Unit has solicited verbal feedback from stakeholders in multiple Health Care-associated Infections/Preventable Adverse Events Advisory Panel meetings. The advisory panel includes hospital infection preventionists, health care quality improvement professionals, hospital and ambulatory surgical center administrators, physicians, and consumers. Panelists also include members of the Texas Medical Association and the Association of Professionals in Infection Control.

Stakeholders provided input regarding the relative importance of the PAEs being reported and recommended the phase-in schedule for reporting that is addressed in the amendments.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item #4.c.

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| Approved by Assistant Commissioner/ Director: | Janna Zumbrun, Assistant Commissioner for Disease Control and Prevention Services Division | Date: | 5/16/14 |
| Presenter: Marilyn Felkner, DrPH | Program: Manager, Emerging and Acute Infectious Disease Branch | Phone No.: | 512-776-6878 |
| Approved by CCEA: | Carolyn Bivens | Date: | 5/16/2014 |

Title 25. Health Services

Part 1. Department of State Health Services

Chapter 200. Reporting of Health Care-Associated Infections and Preventable Adverse Events

Subchapter A. Control of Communicable Diseases

Amendments §§200.1 - 200.4 and §§200.6 - 200.8

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §§200.1 - 200.4 and §§200.6 - 200.8, concerning the reporting of preventable adverse events.

BACKGROUND AND PURPOSE

The amendments are necessary to comply with the Senate Bill (SB) 203, 81st Legislature, Regular Session, 2009, that requires facilities to report preventable adverse events.

SB 203 amended the Health and Safety Code, Chapter 98, Reporting of Health Care-Associated Infections and Preventable Adverse Events, §98.106, Departmental Summary, that the department will compile and make available to the public a summary of health care facilities that reported preventable adverse events by placing this information on the department's website. The department is required to make available to the public a report that includes types of preventable adverse events by facility including the number of deaths or severe harm that resulted while being cared for in a health care facility.

SECTION BY SECTION SUMMARY

An amendment to §200.1 adds definitions to clarify reporting of preventable adverse events.

An amendment to §200.2 clarifies that facilities shall submit preventable adverse event data as specified in §§200.2 - 200.8.

An amendment to §200.3 describes how facilities shall report certain facility specific and preventable adverse event data.

An amendment to §200.4 will clarify how to report NHSN-reported preventable adverse events and designated preventable adverse events.

An amendment to §200.6 defines when to initiate reporting of preventable adverse event data.

An amendment to §200.7 includes the scheduled list of preventable adverse events to be reported by the facilities.

An amendment to §200.8 lists that preventable adverse event data submitted may be corrected during the corrections time schedule.

FISCAL IMPACT

Ms. Janna Zumbrun, Assistant Commissioner, Division for Disease Control and Prevention Services, has determined that for each year for the first five years that the sections will be in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed.

MICRO-BUSINESSES AND SMALL BUSINESSES IMPACT ANALYSIS

Ms. Zumbrun has also determined that for each year of the first five years the sections are in effect, there will be costs to micro-businesses and small businesses such as ambulatory surgical centers or hospitals. The reporting of preventable adverse events places additional resource burden on reporting facilities. Additional staff will be needed to enter and assure quality of the data. For certain facilities, software modifications may be needed in order to efficiently report preventable adverse events to the State. The Texas Hospital Association sought feedback from stakeholders that estimated an annual fiscal impact of \$250,000 per year to implement and maintain reporting requirements for preventable adverse events.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the rules as proposed. There will not be an impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Zumbrun has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections is for the public to be knowledgeable and informed of the number of deaths and severe harm events occurring while being cared for in a health care facility resulting in or associated with preventable adverse events during the reporting period.

REGULATORY ANALYSIS

The department has determined that this proposal is not a “major environmental rule” as defined by Government Code, §2001.0225. “Major environmental rule” is defined to mean a rule with the specific intent to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendments do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, there, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments or questions on the proposal may be submitted to Vickie Gillespie, Preventable Adverse Events Clinical Analyst, Healthcare Safety Program, Division of Disease Control and Prevention Services, Department of State Health Services, Mail Code 1960, P.O. Box 149347, Austin, Texas, 78714-9347, (512) 776-6878 or Vickie.Gillespie@dshs.state.tx.us. Comments will be accepted for 30 days following publication of this proposal in the *Texas Register*. A public hearing will not be held.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the states agencies' authority to adopt.

STATUTORY AUTHORITY

The amendments are authorized by Health and Safety Code, §98.101, which authorizes the Executive Commissioner of the Health and Human Services Commission to implement Chapter 98 by adopting rules; §98.105 which authorizes the Executive Commissioner to modify which procedures are reportable; §98.108 which authorizes the Executive Commissioner to establish the frequency of reporting by rule; and by Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commission of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The amendments affect Government Code, Chapter 531, and Health and Safety Code, Chapters 98 and 1001.

Legend: (Proposed Amendments)

Single Underline = Proposed new language

[Bold, Print, and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§200.1. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) AHRO--Agency for Healthcare Research and Quality.

(2) [(1)] Ambulatory surgical center--A facility licensed under Texas Health and Safety Code, Chapter 243.

(3) APGAR Score--A test designed to quickly evaluate a newborn's physical condition and to determine any immediate need for extra medical or emergency care.

(4) [(2)] Central line--An intravascular catheter that terminates at or close to the heart or in one of the great vessels which is used for infusion, withdrawal of blood or hemodynamic monitoring.

(5) [(3)] CMS--Centers for Medicare and Medicaid Services under the United States Department of Health and Human Services.

(6) [(4)] Comments--Notes or explanations submitted by the health care facilities concerning the department's compilation and summary of the facilities' data that is made available to the public as described in the Texas Health and Safety Code, §98.106.

(7) [(5)] Data--Facility and patient level information reported to the department for the purposes of monitoring health care-associated infections and preventable adverse events.

(8) [(6)] Data summary--Facility level information prepared by the department for each health care facility required to report in this state to facilitate comparisons of risk-adjusted infection rates and preventable adverse events.

(9) [(7)] Department--Department of State Health Services.

(10) [(8)] Device days--The number of patients in a special care setting who have one or more central lines for each day of the month, determined at the same time each day of the reporting quarter.

(11) [(9)] Facility contact--Person identified by the health care facility responsible for coordinating communications related to data submission, verification and approval of data summary.

(12) [(10)] Facility Identification Number--The unique, distinguishable, uniform number used to identify each health care facility.

(13) Fall--A sudden, unintended, uncontrolled downward displacement of a patient's body to the ground or other object.

(14) [(11)] General hospital--A hospital licensed under Texas Health and Safety Code, Chapter 241, or a hospital that provides surgical or obstetrical services and that is maintained or operated by the state.

(15) [(12)] Great vessels--Primary blood vessels to include aorta, pulmonary artery, superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, external iliac veins, common femoral veins, and in neonates, the umbilical artery or umbilical vein.

(16) [(13)] Health care-associated infection (HAI)--Localized or symptomatic condition resulting from an adverse reaction to an infectious agent or its toxins to which a patient is exposed in the course of the delivery of health care to the patient.

(17) [(14)] Health care-associated infection data--Patient level information identifying the patient, procedures and events required by this chapter, infections resulting from those procedures or events, and causative pathogens when laboratory confirmed.

(18) [(15)] Health care facility or facility--A general hospital or ambulatory surgical [surgery] center.

(19) [(16)] ICD-CM--The International Classification of Diseases, Clinical Modification that is used to code and classify morbidity data from the inpatient and outpatient records of hospitals, ambulatory surgical centers, and physician offices.

(20) Incident--A patient safety event that reached the patient, whether or not the patient was harmed.

(21) [(17)] Inpatient Treatment--An admission to an acute care hospital of greater than 24 hours for medical treatment [of a **post operative surgical site infection**].

(22) Medical Gas--A gas used in the medical treatment of a patient such as oxygen, nitrogen or nitrous oxide.

(23) Mild Harm--Bodily or psychological injury results in the minimal symptoms or loss of function, or injury limited to the additional treatment, monitoring and/or increased length of stay.

(24) Moderate Harm--Bodily or psychological injury adversely affecting functional ability or quality of life, but not at the levels of severe harm.

(25) Near Miss--A patient safety event that did not reach the patient.

(26) [(18)] NHSN--[Federal] Centers for Disease Control and Prevention's National Healthcare Safety Network or its successor.

(27) NHSN-reported PAE--a preventable adverse event as defined by NQF or CMS which is reported through NHSN or its successor.

(28) NQF--National Quality Forum.

(29) No Harm--A patient safety incident that reached the patient, but no harm was evident.

(30) PSO--Patient safety organization.

(31) Perinatal--The period from the 20th week of gestation through 4 weeks postpartum.

(32) [(19)] Pediatric and adolescent hospital--A general hospital that specializes in providing services to children and adolescents, as defined in Texas Health and Safety Code, §241.003.

(33) Pressure Ulcer--Localized injury to the skin and/or underlying tissue that usually occurs over a bony prominence as a result of pressure, or pressure in combination with shear and/or friction.

(34) [(20)] PAE--Preventable adverse event. Examples of PAEs are given in Texas Health and Safety Code, §98.1045.

(35) [(21)] Reporting quarters--First quarter: January 1 through March 31; Second quarter: April 1 through June 30; Third quarter: July 1 through September 30; Fourth quarter: October 1 through December 31.

(36) [(22)] Risk adjustment--A statistical method to account for a patient's severity of illness and the likelihood of development of a health care-associated infection (e.g., duration of procedure in minutes, wound class, and American Society of Anesthesiology (ASA) score).

(37) SRE--Serious Reportable Event. Also known as a “never event.”

(38) Severe Harm--bodily or psychological injury that interferes significantly with the functional ability or quality of life.

(39) [(23)] Special care setting--A unit or service of a general, pediatric or adolescent hospital that provides treatment to inpatients who require extraordinary care on a concentrated and continuous basis. The term includes an adult intensive care unit, a burn intensive care unit and a critical care unit.

(40) TxHSN--Texas Health Care Safety Network.

(41) TxHSN-reported PAE--A preventable adverse event as defined in §200.7 of this title (relating to Schedule for HAI and PAE Reporting) reported through the TxHSN portal or its successor.

(42) Unsafe Condition--Any circumstance that increases the probability of a patient safety event.

(43) [(24)] Urinary catheter--As defined by the Centers for Disease Control and Prevention's National Healthcare Safety Network at www.cdc.gov/nhsn or its successor.

(44) [(25)] Urinary tract infection (UTI)--As defined by the Centers for Disease Control and Prevention's National Healthcare Safety Network at www.cdc.gov/nhsn or its successor. [A UTI associated with an indwelling urinary catheter is a catheter associated urinary tract infection (CAUTI)].

(45) [(26)] Validation--The process of comparing data received by the department [submissions] to original patient and facility records to ascertain the accuracy of reported data compared to the case definition [that data submission processes are accurate].

(46) [(27)] Verification--Review of data submitted electronically to assure completeness and internal consistency.

§200.2. General Reporting Guidelines for Health Care-Associated Infection and Preventable Adverse Event Data.

(a) All general hospitals and ambulatory surgical centers in operation during any part of a reporting quarter described in §200.1 of this title (relating to Definitions) shall submit health care-associated infection data (HAI), including whether the HAI contributed to a patient's death, the death of a patient, and designated preventable adverse event (PAE) data as specified in §§200.3 - 200.7 of this title to the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) or its successor. TxHSN-reported PAE information as specified in §200.6 of this title (relating to When to Initiate Reporting) shall be reported via the TxHSN portal or its successor.

(b) - (d) (No change.)

(e) The facility shall ensure that the department has accurate email and phone information for a facility contact. **[(Facilities may provide institutional contact information (e.g., IP@hospital.org, 1-800-INFECTS).]** The facility shall ensure that communications from the department are continuously monitored even if the position is vacant for any reason (vacation, illness, etc.).

§200.3. How to Report.

(a) Facilities shall submit HAI and NHSN-reported PAEs, including whether the HAI or NHSN-reported PAE contributed to a patient's death [**and designated PAE data required by this section**] to NHSN or its successor. Health care facilities shall report TxHSN-reported PAEs through the TxHSN portal or its successor.

(b) Facilities shall comply with the process prescribed by this chapter and NHSN or its successor to allow the department access to HAI data, including whether the HAI contributed to a patient's death, and/or [and] designated PAE data as specified in §§200.3 - 200.7 of this title.

(c) Facilities shall use their facility identification number to identify their facility in the electronic data and correspondence with the department. Each facility meeting the definition of ambulatory surgical center or general hospital as defined in §200.1(2) [**§200.1(1)**] and (15) [(11)] of this title (relating to Definitions) shall have its own facility identification number.

(1) - (3) (No change.)

(d) The department shall notify the facility contact by email 90 calendar days in advance of any change in requirements for reporting HAI data, including whether the HAI contributed to a patient's death, and designated PAE data.

(e) Facilities shall report HAI and NHSN-reported PAE data on patients identified with a surgical site infection associated with a procedure listed in §200.4 of this title (relating to Which Events to Report). Facilities shall report TxHSN-reported PAE data as defined in §200.4 and §200.6 of this title.

(1) For HAI reporting, if the facility treating the patient performed the procedure, the facility shall report the infection to NHSN or its successor according to the surveillance methods described by NHSN or its successor and this chapter. For NHSN-reported PAE reporting, if the event occurred in the facility treating the patient, the facility shall report the event to NHSN or its successor according the surveillance methods described by NHSN or its successor and this chapter.

(2) For PAE reporting, TxHSN-reported PAEs identified at the same facility that the PAE occurred, shall be reported through the TxHSN portal or its successor as described in this chapter.

(3) [(2)] For HAI and NHSN-reported PAE reporting, if [**If**] the facility treating the patient did not perform the procedure [surgery], the treating facility shall notify the facility that performed the procedure, document the notification, and maintain this documentation for audit purposes. The facility that performed the procedure shall verify the data related to the infection [SSI and designated PAE and]. The performing facility shall report the HAI or NHSN-reported PAE [infection] to NHSN or its successor according to the surveillance methods described by NHSN or its successor and this chapter.

(4) For TxHSN-reported PAEs, if the facility that identified the PAE is not the facility responsible for the event, the facility that identified the PAE shall notify the facility where the event occurred, document the notification, and maintain this documentation for audit purposes. The facility in which the event occurred shall report the PAE to TxHSN or its successor according to the methods described by the department and this chapter.

§200.4. Which Events to Report.

(a) - (e) (No change.)

(f) Facilities shall report whether the HAI or the NHSN-reported PAE contributed to a patient's death either directly or by exacerbating an existing disease condition which then led to death.

(g) General hospitals and ambulatory surgical centers shall report any of the following preventable adverse events involving the facility's patient.

(1) A health care-associated adverse condition or event for which the Medicare program will not provide additional payment to the facility under a policy adopted by the federal Centers for Medicare and Medicaid Services.

(2) An event included in the list of adverse events identified by the National Quality Forum.

(3) The executive commissioner may exclude an adverse event from the reporting requirement if the executive commissioner, in consultation with the advisory panel, determines that the adverse event is not an appropriate indicator of a preventable adverse event.

(h) [(g)] Facilities shall also report denominator data as indicated in TxHSN protocols for TxHSN-reported PAEs. For [for] the HAI events identified in this section for calculation of risk adjusted infection rates as required in Texas Health and Safety Code, §98.106(b), [.] NHSN protocols shall be used for the determination of denominator data for HAI and NHSN-reported PAEs. The following facility information shall be entered by the facility for each reporting period.

(1) Number of beds.

(2) Number of surgeries or invasive procedures performed during the reporting period.

(3) Number of patient days.

(i) If a facility has no HAI and/or PAE during the reporting period, facilities shall report this information through NHSN for HAI and NHSN-reported PAEs. Facilities shall report the absence of TxHSN-reported PAEs through the TxHSN portal or its successor.

§200.6. When to Initiate Reporting.

(a) All health care facilities who meet the criteria in §200.4 of this title (relating to Which Events to Report) shall enroll in NHSN within 90 calendar days of the designation of NHSN as the secure electronic interface to report HAI or NHSN-reported PAE data. In addition, all health care facilities shall notify the department to obtain TxHSN user accounts and report TxHSN-reported PAEs through TxHSN or its successor. Facilities will be required to do this within 90 calendar days of when TxHSN-reported PAEs are required to be reported or for newly reporting facilities, within 90 days of becoming eligible to report TxHSN-reported PAEs.

(b) - (g) (No change.)

§200.7. Schedule for HAI and PAE Reporting.

(a) - (c) (No change.)

(d) Health care facilities shall begin reporting TxHSN-reported PAEs data as outlined starting on January 1, 2015.

(1) Facilities will report the following preventable adverse events effective January 1, 2015.

(A) Surgeries or invasive procedures involving a surgery on the wrong site, wrong patient, wrong procedure or a foreign object retained after surgery.

(B) Patient death or severe harm associated with unsafe administration of blood or blood products.

(C) Patient death or severe harm associated with a fall in a health care facility resulting in a fracture, dislocation, intracranial injury, crushing injury, burn or other injury.

(D) Post-operative death of an ASA Class 1 Patient.

(E) Discharge or release of a patient of any age, who is unable to make decisions, to someone other than an authorized person.

(F) Perinatal death or severe harm (maternal or neonatal) associated with labor or deliver in a low-risk pregnancy while being cared for in a health care facility.

(G) Patient death or severe harm resulting from failure to follow up or communicate laboratory, pathology or radiology test results.

(H) Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, wrong gas, or are contaminated by toxic substances.

(I) Patient death or severe harm associated with use of physical restraints or bedrails while being cared for in a health care facility.

(J) Abduction of a patient of any age.

(K) Sexual abuse or assault of a patient within or on the grounds of a health care facility.

(L) Patient death or severe harm of a patient resulting from a physical assault that occurs within or on the grounds of a health care facility.

(M) Patient death or severe harm resulting from the irretrievable loss of an irreplaceable biological specimen.

(N) Vascular Catheter-Associated Infection.

(2) Facilities will report the following preventable adverse events effective January 1, 2016.

(A) Stage III, Stage IV or Unstageable pressure ulcer acquired after admission/presentation to a health care facility.

(B) Patient death or severe harm associated with patient elopement.

(C) Patient suicide, attempted suicide or self-harm that results in severe harm, while being cared for in a health care facility.

(D) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist or other licensed health care provider.

(E) Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) after total knee replacement or after hip replacement.

(F) Patient death or severe harm associated with an electric shock while being cared for in a health care facility.

(G) Patient death or severe harm associated with a burn incurred from any source while being cared for in a health care facility.

(H) Iatrogenic Pneumothorax with venous catheterization.

(I) Patient death or severe harm associated with the introduction of a metallic object into the MRI area.

(3) Facilities will report the following preventable adverse events effective January 1, 2017.

(A) Patient death or severe harm associated with intravascular air embolism that occurs while being cared for in a health care facility.

(B) Poor glycemic control resulting in diabetic ketoacidosis.

(C) Poor glycemic controls resulting in nonketonic hyperosmolar coma.

(D) Poor glycemic control resulting in hypoglycemic coma.

(E) Poor glycemic control resulting in secondary diabetes with ketoacidosis.

(F) Poor glycemic control resulting in secondary diabetes with hyperosmolarity.

(G) Artificial insemination with the wrong donor sperm or wrong egg.

(H) Patient death or severe harm associated with the use of contaminated drugs/devices or biologics provided by the health care facility.

(I) Patient death or severe harm associated with the use or function of a device in patient care, in which the device is used or functions other than as intended.

(J) Patient death or severe harm associated with a medication error.

(K) Surgical site infections following a spinal procedure, shoulder procedure, elbow procedure, laparoscopic gastric bypass, gastroenterostomy, laparoscopic gastric restrictive surgery or cardiac implantable electronic device.

(4) Amendments to this list of preventable adverse events may be adopted at the discretion of the executive commissioner as recommended by CMS and NQF.

§200.8. Verification of Health Care-Associated Infection and Preventable Adverse Event Data and Correction of Errors.

(a) (No change.)

(b) Correction of Errors and Disputes.

(1) Facilities shall correct all identified errors, including data determined to be missing, and resubmit the corrected data through NHSN or its successor for HAI and NHSN-reported PAEs. Facilities shall correct data for TxHSN-reported PAEs through the TxHSN portal or its successor.

(2) - (3) (No change.)

(4) Data corrections that occur following publication of a data summary shall be submitted to NHSN or its successor for HAI and NHSN-reported PAEs. Data corrections for TxHSN-reported PAEs that occur following publication of a data summary shall be submitted through TxHSN or its successor.

(c) - (d) (No change.)